DSJ1&2-PR Exh 601

DRAFT Options for Controlled Substance Regulatory and Related Activity
for Review Purposes Only -- Not for External Circulation

✓✓✓ = Very high interest ✓✓ = Some interest ✓ = Low interest 0 = don't do

	Potential Action	Description	RAC Comments	Rating
1.	Update the ICG	HDMA finalized the ICG in October, 2008, but much has evolved since then. Many distributors conduct due diligence and suspicious orders monitoring using alternative or expanded approaches. The ICG could be updated to reflect these approaches.	RAC believes this should be a lower priority activity. If we update it, make it "high level" and broad to allow flexibility.	✓
2.	Petition DEA for a Regulation to Clarify Suspicious Orders (SO) and/or SO Monitoring Expectations?	We discussed this idea in the past but did not act on it. However, there have been considerable developments since our last discussion. Also, if we were to request legislation clarifying SO monitoring requirements, potential sponsors would likely ask us if we've first asked DEA to clarify their rules and what is lacking currently.	Favored this option above all the others. • Unlikely that DEA would create such a regulation. Therefore, low risk of resulting in something overly restrictive or difficult to follow. • A "good ask" -- the optics would be positive. We go on the record as asking for clarity. • Recognized this may tie into what is done on the Hill, or in a PR campaign as external pressure may be desirable and/or a legislator may use it as the basis of a new Bill. • Some went so far as to state we *should* do this. • Urged HDMA to carefully articulate (1) what we believe DEA should address, and (2) DEA should only inspect/enforce against what is specified in the regulations.	✓✓✓

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3.	Collect ARCOS data	HDMA would manage a 3rd party vendor to collect/analyze ARCOS data ourselves. Support Distributors SO monitoring by providing the types of analyses we had hoped DEA would provide.	This might be helpful. However, there are likely significant limitations. Thus, not strongly favored. • 100% participation is needed to make it truly useful – but it's unlikely that secondaries would participate. • A "huge effort".	✓
4.	Create a Customer Algorithm and Thresholds	Develop a system identify "suspicious" customers. Consider each customer's size, patient demographics, proximity to healthcare providers, etc. Potentially include a "threshold" number for HDMA members to support their customer evaluations.	RAC does not favor. Likely even more difficult than collecting/analyzing ARCOS data noted above. Not likely to result in useful information. *Reviewers: we didn't discuss this one very much, but no one seemed to jump on it. Does the above comment accurately reflect your views?*	✓ or 0
5.	Create a 3rd Party Audit Program	The 3rd party would audit HDMA members' compliance at the member's request and pursuant to DEA-reviewed protocols. Intended to give both input into CS monitoring programs, and some buffer against DEA action.	RAC does not favor. • "We're already being audited by DEA" but their audits aren't a useful predictor/indicator of what the wholesale distributor should be doing. So a 3rd party wouldn't add much. • Many of us have already had 3rd party audits.	0
6.	Use PDMP Data to Help Distributors with Customer Evaluations	Look into whether the NABP PDMP system could be amended to provide HDMA's members with customer information. This was not mentioned to the Board, it's a new suggestion since then. Could be an outgrowth/alternative to collecting ARCOS data.	Might be worth while looking into, but might also have limitations. • Pro: Appropriate - involves information from those that with greater patient responsibility. • Con: Most states have strict rules securing/limiting data access (e.g. only law enforcement and/or only prescribers, pharmacies).	✓✓

Note, of the last 4 items, most RAC members thought # 3 & 6 had more potential than 4 or 5.